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SURGICAL INSTRUMENT SERVICE COMPANY, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

**SURGICAL INSTRUMENT SERVICE
COMPANY, INC.**

Plaintiff/Counter-Defendant,

v.

INTUITIVE SURGICAL, INC.,

Defendant/Counterclaimant.

Case No. 3:21-cv-03496-VC

Honorable Vince Chhabria

**DECLARATION OF JOSHUA VAN
HOVEN IN SUPPORT OF PLAINTIFF
SURGICAL INSTRUMENT SERVICE
COMPANY, INC.'S MOTION FOR
PARTIAL SUMMARY JUDGMENT**

Hearing: June 8, 2023

Time: 10 AM PT

Courtroom: Courtroom 5, 17th Floor

Judge: The Honorable Vince Chhabria

Complaint Filed: May 10, 2021

1 I, JOSHUA VAN HOVEN, declare as follows:

2 I am an attorney at the law firm of MCCAULLEY LAW GROUP LLC, attorneys for
3 Plaintiff SURGICAL INSTRUMENT SERVICE COMPANY, INC. (“SIS”) in this matter. I
4 have personal knowledge of the matters set forth herein, unless otherwise noted.

5 1. Attached as Exhibit 1 is a true and correct copy of Intuitive’s Form 10-K for the
6 fiscal year ended December 31, 2022.

7 2. Attached as Exhibit 2 is a true and correct copy of United States Patent No.
8 5,792,135.

9 3. Attached as Exhibit 3 is a true and correct copy of excerpts of the deposition of
10 Robert Howe, an expert for Defendant Intuitive Surgical, Inc. (“Intuitive”) in this case,
11 which was taken on February 24, 2023.

12 4. Attached as Exhibit 4 is a true and correct copy of a Patent Notice pursuant to 35
13 U.S. Code § 287 obtained from Intuitive’s website on March 21, 2023.

14 5. Attached as Exhibit 5 is a true and correct copy of excerpts of the deposition of
15 Grant Duque, Intuitive’s Senior Director of Core Instruments Design and Product
16 Engineering, which was taken on November 8, 2022.

17 6. Attached as Exhibit 6 is a true and correct copy of excerpts of the Expert Report of
18 Amandeep Mahal, M.D., an SIS expert in this case, which is dated December 1, 2022.

19 7. Attached as Exhibit 7 is a true and correct copy of relevant excerpts of the
20 deposition of Sharathchandra “Shark” Somayaji, Intuitive’s Senior Director Manufacturing
21 Engineering, which was taken on November 4, 2022.

22 8. Attached as Exhibit 8 is a true and correct copy of excerpts of the deposition of
23 Daniel Jones, Intuitive’s Director of External Affairs, which was taken on November 10,
24 2022.

25 9. Attached as Exhibit 9 is a true and correct copy of the Expert Report of Russell L.
26 Lamb, Ph.D., an SIS expert in this case, which is dated December 2, 2022.

27 10. Attached as Exhibit 10 is a true and correct copy of the Expert Report of T. Kim
28 Parnell, Ph.D., an SIS expert in this case, which is dated January 18, 2023.

11. Attached as Exhibit 11 is a true and correct copy of excerpts of the 30(b)(6) deposition of Grant Duque, which was taken on November 8, 2022.

12. Attached as Exhibit 12 is a true and correct copy of a July 21, 2022. Intuitive Letter, which was produced by Intuitive in this case and bates-labeled as Intuitive-02066979-Intuitive-02067059.

13. Attached as Exhibit 13 is a true and correct copy of excerpts of the deposition of Maxwell Meng, M.D., an Intuitive expert in this case, which was taken on March 7, 2023.

14. Attached as Exhibit 14 is a true and correct copy of excerpts of the deposition of Colin Morales, an Intuitive 30(b)(6) witness, which was taken on November 9, 2022.

15. Attached as Exhibit 15 is a true and correct copy of a PowerPoint entitled “Gen4 Instrument Refurbishment Pilot”, which was produced by Intuitive in this case and bates-labeled Intuitive-00626597- Intuitive-00626616.

16. Attached as Exhibit 16 is a true and correct copy of a PowerPoint entitled “Core Instrument Strategy”, which was produced by Intuitive in this case and bates-labeled Intuitive-00671209-Intuitive00671220.

17. Attached as Exhibit 17 is a printout of the “About Us” webpage of SIS, available at <https://sis-usa.com/about/> .

18. Attached as Exhibit 18 is a true and correct copy of excerpts of the 30(b)(1) deposition of Greg Posdal, which was taken on November 1, 2022.

19. Attached as Exhibit 19 is a true and correct copy of excerpts of the 30(b)(1) deposition of Keith Johnson, which was taken on October 27, 2022.

20. Attached as Exhibit 20 is a true and correct copy of excerpts of the 30(b)(6) deposition of Keith Johnson, which was taken on October 27, 2022.

21. Attached as Exhibit 21 is a true and correct copy of a document labeled “da Vinci® EndoWrist® Repair FAQs” and bates-labeled SIS095119-39.

22. Attached as Exhibit 22 is a true and correct copy of excerpts of the deposition of Clifton Earl Parker, which was taken on October 27, 2022.

23. Attached as Exhibit 23 is a true and correct copy of excerpts of the 30(b)(6)

1 deposition of Greg Posdal, which was taken on November 1, 2022.

2 24. Attached as Exhibit 24 is a true and correct copy of a November 26, 2019, Intuitive
3 Letter, which was produced by Intuitive in this case and bates-labeled Intuitive-00049154-
4 Intuitive-00049156.

5 25. Attached as Exhibit 25 is a true and correct copy of a February 14, 2020, Intuitive
6 Letter, which was produced by Intuitive in this case and bates-labeled Intuitive-00986535-
7 Intuitive-00986537.

8 26. Attached as Exhibit 26 is a true and correct copy of a January 29, 2020, Intuitive
9 Letter, which was produced by Intuitive in this case and bates-labeled Intuitive-00552745-
10 Intuitive-00552759.

11 27. Attached as Exhibit 27 is a true and correct copy of the Pure Food and Drug Act of
12 1906. 34 Stat. 768, Ch. 3915.

13 28. Attached as Exhibit 28 is a true and correct copy of the Federal Food, Drug and
14 Cosmetic Act of 1938. 52 Stat. 1040.

15 29. Attached as Exhibit 29 is a true and correct copy of a Publication entitled “Medical
16 Device and Radiological Health Regulations Come of Age”, which was written by Carol
17 Rados and published in the FDA Consumer magazine in 2006.

18 30. Attached as Exhibit 30 is a true and correct copy of the Medical Device
19 Amendments of 1976. 90 Stat. 539.

20 31. Attached as Exhibit 31 is a true and correct copy of the Safe Medical Devices Act of
21 1990. 104 Stat. 4511.

22 32. Attached as Exhibit 32 is a true and correct copy of the Congressional Record
23 Volume 148, Issue 137 – Part II, which is dated July 12, 2002.

24 33. Attached as Exhibit 33 is a true and correct copy of the Medical Device User Fee
25 and Modernization Act of 2022. 116 Stat. 1588.

26 34. Attached as Exhibit 34 is a true and correct copy of the Medical Device Servicing
27 Safety and Accountability Act, as introduced. H. R. 2118.

28 35. Attached as Exhibit 35 is a true and correct copy of the FDA Reauthorization Act of

2017 as introduced. H. R. 2430.

36. Attached as Exhibit 36 is a true and correct copy of the FDA Reauthorization Act of 2017 as passed. 131 Stat. 1005.

37. Attached as Exhibit 37 is a true and correct copy of the Clarifying Remanufacturing to Protect Patient Safety Act of 2022. H. R. 7253.

38. Attached as Exhibit 38 is a true and correct copy of a listing of all actions related to the Clarifying Remanufacturing to Protect Patient Safety Act of 2022. H. R. 7253.

39. Attached as Exhibit 39 is a true and correct copy of the Federal Register of October 7, 1996. Vol. 61, No. 195

40. Attached as Exhibit 40 is a true and correct copy of the Federal Register of December 23, 1997. Vol. 62, No. 246.

41. Attached as Exhibit 41 is a true and correct copy of the Federal Register of March 4, 2016. Vol. 81, No. 43.

42. Attached as Exhibit 42 is a true and correct copy of the Federal Register of July 18, 2016. Vol. 81, No. 137.

43. Attached as Exhibit 43 is a true and correct copy of the transcription of the FDA October 27, 2016 Workshop on Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Services of Medical Devices.

44. Attached as Exhibit 44 is a true and correct copy of the FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Device, which is dated May 2018.

45. Attached as Exhibit 45 is a true and correct copy of a White Paper entitled “Evaluating Whether Activities are Servicing or Remanufacturing”, which was published by the FDA in May 2018.

46. Attached as Exhibit 46 is a true and correct copy of the Draft Guidance for Industry and Food and Drug Administration Staff, which was issued by the FDA on June 24, 2021.

47. Attached as Exhibit 47 is e-mail correspondence between FDA and Rebotix, starting February 28, 2020, bates-labeled REBOTIX171224- REBOTIX171226, which was publicly filed in *Rebotix Repair LLC v. Intuitive Surgical, Inc.*, 8:20-cv-2274 (M.D. Fla.).

1 48. Attached as Exhibit 48 is e-mail correspondence between FDA and Rebotix, starting
2 December 13, 2021, which was publicly filed in *Rebotix Repair LLC v. Intuitive Surgical,*
3 *Inc.*, 8:20-cv-2274 (M.D. Fla.).

4 49. Attached as Exhibit 49 is a true and correct copy of excerpts of the deposition of
5 Stan Hamilton, which was taken on November 4, 2022.

6 50. Attached as Exhibit 50 is a true and correct copy of excerpts of Christy Foreman,
7 MBE, served by Intuitive in this matter.

8
9 I declare under penalty of perjury that the foregoing is true and correct.

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11 EXECUTED the 23rd day of March, 2023 in San Ramon, California.

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13 /s/ Joshua Van Hoven
14 Joshua Van Hoven
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